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| 09/534,861      | 03/24/2000  | Josephus Christianus Maria Smeekens | ARNO115313          | 2637             |

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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC  
1420 FIFTH AVENUE  
SUITE 2800  
SEATTLE, WA 98101-2347

EXAMINER

FOX, DAVID T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 07/01/2002

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Please find below and or attached an Office communication concerning this application or proceeding.

# Office Action Summary

|                               |                                |
|-------------------------------|--------------------------------|
| Application No.<br>09/534,861 | Applicant(s)<br>Sneekens et al |
| Examiner<br>Fox               | Group Art Unit<br>1638         |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

☒ Responsive to communication(s) filed on 3/26/02

☐ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☒ received in Application No. (Series Code/Serial Number) 08/479,470
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).
- \*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- Other \_\_\_\_\_

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The substitute specification of 15 January 2002 has been entered.

The Sequence Listing incorrectly lists application Serial No. 09/193,385 as a parent of the instant application. See page 1 of the substitute specification for the correct continuity data.

Applicants are requested to submit a new copy of the Sequence Listing, in both paper and computer readable formats, with the corrected continuity data.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,147,280. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to utilize the method for obtaining oligosaccharides comprising plant transformation as claimed in the patent to obtain the method for obtaining oligosaccharides comprising plant transformation as claimed in the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to plant transformation with the native barley fructosyltransferase gene or mutant bacterial fructosyltransferase genes for the production of oligosaccharides, does not reasonably provide enablement for isolated plant fructosyltransferase genes from any other species, for the mutation of any plant fructosyltransferase gene to lower the degree of polymerization of the end product, or for the use of any other gene encoding any other enzyme for the production of oligosaccharides in transformed plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification only provides guidance for the isolation and characterization of a barley fructosyltransferase gene and a native *Streptococcus mutans ftf* gene which encode enzymes which inherently produce fructans of low polymerization (see, e.g., page 4, line 21-page 5, line 23 and Figure 11 of the specification). In addition, the specification only provides guidance for the

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mutation of bacterial fructosyltransferase genes for the reduction of polymerization of the end products. No guidance is provided for the isolation or characterization of any other plant gene, or for the mutation of any plant gene for the reduction of polymerization of the end product. In addition, no guidance is provided for the identification of any other enzyme involved in the production of oligosaccharides, the identification and isolation of any gene encoding it from any organism, or its evaluation to produce oligosaccharides in transformed plants. In contrast, the claim is broadly drawn to plant transformation with any gene from any source which confers oligosaccharide producing ability.

The isolation, identification and characterization of fructosyltransferase genes is unpredictable, given the lack of existence of the end product, and therefore the gene encoding the necessary enzyme, in many higher plants (see, e.g., page 6 of the specification, lines 30-31). See also Smeekens et al (1991), page 568, column 1, second and third full paragraphs, where different workers have reported conflicting results regarding the existence of discrete fructosyltransferase enzymes versus the existence of other bifunctional enzymes which also possess fructosyltransferase activity, and wherein the isolation of a plant fructosyltransferase was not achieved in several plant species.

Furthermore, regarding the two exemplified microbial enzymes, the gene encoding each possesses complex regulation and complex expression products which are not completely understood (see, e.g., Shiroza et al [1988], page 810, column 1, penultimate paragraph; page 813, column 2, bottom two paragraphs; page 814, column 2; page 815, column 1, top paragraph).

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Finally, the substitution of sequences in fructosyltransferase genes is unpredictable, as evidenced by the complete alteration in enzyme activity and end product following the substitution of a single amino acid (see, e.g., Fuchs [1991], page 556, column 1, first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, obtain and evaluate a multitude of non-exemplified plant fructosyltransferase genes, or a multitude of mutations of a multitude of plant fructosyltransferase genes to be expressed in transformed plants. Undue experimentation would have also been required to identify a multitude of non-exemplified enzymes involved in oligosaccharide synthesis, to identify and isolate the genes encoding them, and to evaluate the genes for their ability to confer oligosaccharide-synthesizing ability to transgenic plants.

See Ex parte Forman, 230 USPQ 546, 547 (PTO Bd. App. Int. 1986), where it was taught that "the disclosure of a patent application must enable practice of the invention claimed without undue experimentation", wherein factors involved in the determination of undue experimentation were deemed to include "the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims."

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See also In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification only provides guidance for the isolation and characterization of barley and bacterial fructosyltransferase genes. In contrast, the claims are broadly drawn to a multitude of genes of any sequence and from any species, which encode a multitude of enzymes of any sequence, and a method for their use.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the broadly claimed genus. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time it was made.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the

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description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 89/12386 (CALGENE).

The claim is drawn to a method for producing oligosaccharides in transgenic plants comprising plant cell transformation with a gene conferring oligosaccharide synthesis, wherein oligosaccharides are defined in the paragraph bridging pages 1 and 2 of specification as molecules comprising two or more monosaccharides including fructose and glucose, wherein desirable oligosaccharides are composed of up to 16 monosaccharides.

CALGENE teaches tobacco plant transformation with a vector comprising the plant-expressible MAS promoter and terminator and the *B. subtilis sacB* fructosyltransferase gene, wherein said transformation is advantageous for the modified accumulation of non-degradable carbohydrates therein (see, e.g., page 2, lines 20-36; page 6, line 4-page 7, line 24; page 8, lines 5-32; page 11, lines 8-25; page 12; page 13, lines 1-11; page 32, lines 21-37; page 33, lines 1-16; page 38, lines 15-32;



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page 43, lines 29-37; pages 44-46; pages 50-53; claims 1-12). CALGENE also teaches the use of a transit peptide-encoding sequence for targeting to a specific tissue or cellular location (see, e.g., page 6, lines 30-34; page 12, lines 2-10; page 45, line 19-page 49, line 28), and suggests the use of fructosyltransferase genes (see, e.g., page 9, lines 24-35).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 26, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written over the printed name and group number.